

REMARKS/ARGUMENTS

New Claims 20 and 21 are supported by specification page 5, line 10. No new matter is added.

The rejection over Cavallotti, Barnes Bianchi and Reinhard is traversed.

The present inventors have discovered (and solved) a problem not recognized in the art - that, in the preparation of liquid formulations with a high concentration of imidoalkanepercarboxylic acids in either the absence of surfactants or in the presence of anionic surfactants, starting with peracids in  $\alpha$  form and in the stage for conversion of the acid from the  $\alpha$  form to the  $\beta$  form, the viscosity of the preparations increases uncontrollably and the formulation converts from an aqueous dispersion to a mass of pasty consistency. See specification page 6, lines 12ff. As explained there, this pasty mass cannot be used as a liquid formulation and cannot take advantage of the bleaching and disinfecting uses of imidoalkanepercarboxylic acid dispersions.

The inventors solved this unrecognized problem by providing and using an aqueous dispersion comprising water, 7% to 40% of at least one imidoalkanepercarboxylic acid in the  $\beta$ -crystal form having the general formula (I) herein, and from 0.005% - 0.3% of a nonionic surfactant. That is, they found that their dispersion, contrary to those with no surfactants or with anionic surfactants, provides a dispersion that is useful as a liquid formulation and that has a viscosity of not more than 2000 mPa.sec at 25°C, a dissolution time that is not more than 5 minutes at 40°C or more than 15 minutes at 18°C, and a stable viscosity that does not vary by more than 300 mPa.sec at 40°C for seven days.

This solution of a problem unrecognized in the art is patentable, even when the solution itself is known. This fact was recently emphasized by the USPTO in its most recent obviousness guidelines by reference to the case In re Omeprazole Patent Litigation, 536 F.3d 1361 (Fed. Cir. 2008) and the following teaching point:

Even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.

In the USPTO Guidelines (75 Fed. Reg. 53644), the Omeprazole case is explained as follows (emphasis added):

The case of *In re Omeprazole Patent Litigation* is one in which the claims in question were found to be nonobvious in the context of an argument to combine prior art elements. The invention involved applying enteric coatings to a drug in pill form for the purpose of ensuring that the drug did not disintegrate before reaching its intended site of action. The drug at issue was omeprazole, the generic name for gastric acid inhibitor marketed as PrilosecR. The claimed formulation included two layers of coatings over the active ingredient.

The district court found that Astra's patent in suit was infringed by defendants Apotex and Impax. The district court rejected Apotex's defense that the patents were invalid for obviousness. Apotex had argued that the claimed invention was obvious because coated omeprazole tablets were known from a prior art reference, and because secondary subcoatings in pharmaceutical preparations generally were also known. There was no evidence of unpredictability associated with applying two different enteric coatings to omeprazole. However, Astra's reason for applying an intervening subcoating between the prior art coating and omeprazole had been that the prior art coating was actually interacting with omeprazole, thereby contributing to undesirable degradation of the active ingredient. This degradation of omeprazole by interaction with the prior art coating had not been recognized in the prior art.

Therefore, the district court reasoned that based on the evidence available, a person of ordinary skill in the art would have had no reason to include a subcoating in an omeprazole pill formulation.

The Federal Circuit affirmed the district court's decision that the claimed invention was not obvious. Even though subcoatings for enteric drug formulation were known, and there was no evidence of undue technical hurdles or lack of a reasonable expectation of success, the formulation was nevertheless not obvious because the flaws in the prior art formulation that had prompted the modification had not been recognized.

Thus there would have been no reason to modify the initial formulation, even though the modification could have been done. Moreover, a person of skill in the art likely would have chosen a different modification even if he or she had recognized the problem.

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The Omeprazole case can also be analyzed in view of the discovery of a previously unknown problem by the patentee. If the adverse interaction between active agent and coating had been known, it might well have been obvious to use a subcoating. However, since the problem had not been previously known, there would have been no reason to incur additional time and expense to add another layer, even though the addition would have been technologically possible. This is true because the prior art of record failed to mention any stability problem, despite the acknowledgment during testimony at trial that there was a

known theoretical reason that omeprazole might be subject to degradation in the presence of the known coating material.

In the present case, as in the Omeprazole case, the claimed invention solves a problem that was not recognized in the prior art, and the solution to this problem is similarly patentable.

Cavallotti, the closest art, makes imidoalkanepercarboxylic acids and is interested in providing these acids with a relatively constant water content of 8-12% (page 2, lines 36-37, page 4, lines 55-57, page 5, lines 19-21). He found out that he can do this by melting an imidoalkanepercarboxylic acid in excess water, making a eutectic imidoalkanepercarboxylic acid/water mixture, and decanting. See, e.g., Examples 1-7 at page 5, lines 56ff.

“Sequestering substances” can be added, none of which are nonionic surfactants. See page 5, lines 10-15 of the reference. Notably, the final product imidoalkanepercarboxylic acid only contains approximately 10% water, 90% imidoalkanepercarboxylic acid.

Certainly Cavallotti’s initial, non- eutectic mixture of imidoalkanepercarboxylic acid and water has no non-ionic surfactant present, nor is any suggested, nor would anyone want to stabilize this mixture since Cavallotti uses it to form a eutectic mixture by melting the peracid in the water and decanting. Thus, Cavallotti is just like the prior art described in the specification - imidoalkanepercarboxylic acids in water in either the absence of surfactants or in the presence of anionic surfactants<sup>1</sup> - whose viscosity would increase uncontrollably and convert from an aqueous dispersion to a mass of pasty consistency just like the prior art described in the specification.

Recognizing the deficiency in Cavallotti, the Examiner has taken the position that it would have been obvious to add the nonionic surfactant of Barnes or Reinhardt to the Cavallotti “liquid formulation after the imidoalkane percarboxylic acids have been prepared and isolated by the procedure as taught by Cavallotti.” See page 13, lines 7-11 of the

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<sup>1</sup> Note that Cavallotti’s sequestering agents are carboxylic acids.

outstanding Official Action. Even if this were correct, which it is not, such addition would provide a composition with about 10% water, 88% imidoalkanepercarboxylic acid, and 1-2% nonionic surfactant.<sup>2</sup> Such a composition would not be a dispersion,<sup>3</sup> would not comprise 7% to 40% of at least one imidoalkanepercarboxylic acid in the  $\beta$ -crystal form having the general formula (I) herein, and would not comprise from 0.005% - 0.3% of a nonionic surfactant. Thus, even if there were motivation to add a nonionic surfactant to the Cavallotti product and reduce the amount thereof from that suggested by Barnes and Reinhardt to that presently claimed, the claimed dispersion would not be provided.

In addition to this, there is no reason one of ordinary skill in the art would modify Cavallotti by adding a nonionic surfactant. Adding a surfactant in the amount of Barnes or Reinhardt would render Cavallotti unsatisfactory for its intended purpose and change the principle of operation of the reference, as the surfactant would at a minimum hinder the separation of the eutectic composition from the water and make decantation more difficult if not impossible - decantation, Cavallotti's method for separating the eutectic mixture, depends on phase separation. See, e.g., page 6, top, of Cavallotti. Surfactants are used to homogenize disparate phases.

For these reasons and in view of the Omeprazole case, discussed above, the rejection over Cavallotti and Barnes as supplemented by Bianchi and Reinhard should be reconsidered and withdrawn.

Applicants traverse the double patenting rejections over U.S. 7,468,387 and application Serial No. 12/039,797.<sup>4</sup>

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<sup>2</sup> See page 6, lines 5-6 of Barnes (2-50% surfactant) and col. 3, lines 54-57 of Reinhardt (1-50% surfactant)

<sup>3</sup> The Cavallotti product as isolated is a solid eutectic and has only about 10% water, see above.

<sup>4</sup> The Advisory Action dated October 26, 2010 does not discuss the double patenting rejection over U.S. 7,468,387. While believed to be withdrawn, Applicants have included their prior traversal for completeness of the record.

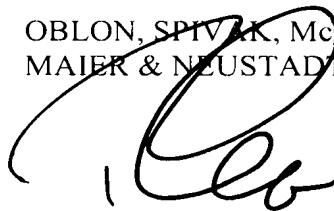
Nothing in the claims of U.S. 7,468,387 (Bianchi) suggest an aqueous dispersion or a nonionic surfactant, as claimed herein. The fact that the claims of U.S. 7,468,387 and the claims pending herein may have one element in common is insufficient basis for a double patenting rejection. The claims herein must be obvious over the claims of the cited U.S. patent for double patenting to lie. Bianchi has not been applied against the claims above as establishing obviousness, but rather has been cited for technical support as describing alpha and beta forms of imidoalkanepercarboxylic acids. It thus should not be applied against the claims for double patenting for the same reasons.

With regard to application Serial No. 12/039,797, this application is clearly later-filed. According to MPEP 804, as this provisional nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the earlier filed of the two pending applications the examiner should withdraw the rejection and permit this earlier-filed application to issue as a patent without a terminal disclaimer.

For the reasons stated above Applicants respectfully submit that this case is in condition for allowance. Early notification to this effect is earnestly solicited.

Respectfully submitted,

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